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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,111	CLANCY ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 23-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,23,24 and 29-56* is/are rejected.

7)☒ Claim(s) *25-28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/28/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 23-56 are pending.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/979,594, filed on March 8, 2002. ***Information Disclosure Statement***

2. The information disclosure statement filed October 28, 2003 has been considered.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 23 and 24, 33-35 are provisionally rejected under the judicially created doctrine of double patenting over claims 1, 10 and 15 of copending Application No. 10/332,112. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

The instantly claimed invention measures IgG2, in any type of sample, and correlated the determined level with a reduction of IgG2 relative to a control value, while the claimed methods of 10/332,112 utilize a saliva sample (see 10/332,112, claim 1); the instantly claimed method is broader in scope that the copending application's claim. The copending species of 10/332,112 anticipates the instantly claimed genus.

The instantly claimed invention measures IL-4 levels in a sample and correlates increased levels with a clinical status relative to a control value, while the claimed methods of 10/332,112 correlate a reduced level or an increased level of IL-4 with clinical status relative to a control value (see 10/332,112, claim 10); the instantly claimed method does not require the values to correlate with eradication of infection status, and is therefore broader in scope that the copending application's claim. The copending species of 10/332,112 anticipates the instantly claimed genus.

The instantly claimed invention measures Interferon-gamma levels in a sample and correlates reduced levels with a clinical status relative to a control value, while the claimed methods of 10/332,112 correlate a reduced level or an increased level of Interferon-gamma with clinical status relative to a control value (see 10/332,112, claim 10); the instantly claimed method does not require the values to correlate with eradication of infection status, and is therefore broader in scope that the copending application's claim. The copending species of 10/332,112 anticipates the instantly claimed genus. Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Objections

5. Claims 25-28 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should depend from only a single claim or multiple claims in the alternative and not multiple claims simultaneously; claims 25-28 depend from two claims simultaneously. See MPEP § 608.01(n). Accordingly, the claims 25-28 will not been further treated on the merits.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36-38, 43-44, 51-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 36-38 recited the phrase "can be performed simultaneously with, a method which provides an indication of H.pylori status". The method is functionally defined based upon the relative term "indication of H.pylori status". How does H. pylori status define what method steps and reagents are used to carry out the additional methods step? What kind of indication defines H.pylori status? The method is a method that analyses samples from H.pylori infected subjects (subject defined in independent claims 1, 23 and 24). What other H.pylori status does the subject have if it is not "infected"? The scope of what is being claimed is unclear in light of the method not reciting a methods step, and only functionally defining a method that produces any type of indication to determine any type of H.pylori status, the status not necessarily being any different from the status of the patient from whom the sample was originally obtained. What are the meets and bounds of the term "status" in light of the fact that the subjects' status is already known to be one of infection ? What types of status are intended by the recitation of this combination of claim limitations? Claims 36-38 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the reagents used in the method that produce an indication of H.pylori status. The indication is not structurally defined by any specific type of reagent or positively recited methods step to determine status.

9. Claim 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: anti-gammaIFN antibodies and anti-IL-4 antibodies. The instant Specification does not define how any antibody level is directly or indirectly indicative of IL-4 or gammaIFN. While an antibody assay could be carried out to detect antibodies, the antibodies of the claimed invention are not so claimed to be specific for any antigen. The assay of these claimed is non-specific for the analytes recited, and therefore the essential elements of the claimed method have been omitted. In re Mayhew, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). See also MPEP § 2164.08(c). Such essential matter may include missing elements, steps or necessary structural cooperative relationships of elements described by the applicant(s) as necessary to practice the invention.

10. Claims 51 and 52 depend from claim 48 which recites the phrase "IgG2 anti-H.pylori antibody- and/or gammaIFN- and/or IL-4-producing cells in the subject's blood". Claim 48 provides antecedent basis for the detection of IgG2 antibody in blood, gammaIFN in blood and IL-4-producing cells in blood. Claim 51 determines "the frequency of IgG2 anti-H.pylori antibody-producing cells"; this phrase lacks antecedent basis in claim 48 from which it depends. Claim 52 determines "the frequency of gammaIFN-producing cells'; this phrase lacks antecedent basis in claim 48 from which it depends. The term "IL-4-producing cells", recited in claim 48 modifies IL-4 and not the phrases "IgG2 anti-H.pylori antibody-" nor "gammaIFN-". Claim 48 determines "the frequency of IgG2 anti-H.pylori antibodies" or "gammaIFN" in blood"; these analytes clearly can be determined with an ELISA or immunoassay.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1, 29, 33, 36, 39, 42, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Steer et al (1987)

13. **Instant claims 1, 29, 33, 39, 42, 45:** Steer discloses the instantly claimed invention directed to a method that comprises the steps of:

a) **determination of IgG2** (abstract, page 255, "Micro ELISA techniques"; Table 3, page 257) in a biological blood (page 254, paragraph 3 "blood collected for sera") sample from a patient suspected of having H.pylori infection (also known as Campylobacter pyloridis).

b) **comparison of the IgG2 with a predetermined control level** (the control being a patient with gastritis for a patient with an ulcer, wherein the level of IgG2 evidenced a reduction due to progression of disease, see Table 3, page 257).

Instant claim 36: the method was carried out in simultaneously with histological analysis to provide an indication of H.pylori status (see page 254, paragraphs 4-6 and Table 1).

The reference inherently anticipates the instantly claimed method.

Please Note: The examiner is reading the phrase "in the subject's blood", recited in claim 48, to include serum, plasma, and whole blood samples and may also include the analysis of cells associated with blood, specifically T- and B- lymphocytes, plasma cells.

14. Claims 1, 29, 33, 36, 39, 42, 45, 48-49,50 are rejected under 35 U.S.C. 102(b) as being anticipated by Alison Rose Stacey (Dissertation, "Human Immune responses to Helicobacter pylori infection", July 1994) .

15. **Instant claims 1, 29, 33, 48:** Stacey discloses the instantly claimed invention directed to a method (see page 216, paragraph 2 "IgG2 antibodies are particularly associated with chronic bacterial infections"; page 109, paragraph 3;see page 40, Group 4 and 5) that comprises the steps of:

a) **determination of IgG2** (see page 61, section 2.9.4) in a biological blood serum (see page 61, lines 1-3) or gastric mucosa (see page 59, paragraph 2, section 2.9) sample.

The serum and gastric mucosa samples were obtained from an H.pylori infected subject (see title) and compared with a standard curve control (see page 60, section 2.9.2), as well as compared with H.pylori antibody negative sera (see page 78, Figure 3.2 and page 79, section 3.1.3 both paragraphs)

Additionally the reference discloses the utilization of other types of assay controls at page 29, section 1.6.1, paragraphs 2-3; Chapter 2, pages 38-71, page 60, section 2.92; and page 80, Figure 3; see page 79, section 3.1.3, paragraph 2: "threshold of sero-positivity for IgG subclasses" "9ug/ml for IgG2".

b) **comparison of the IgG2 with a predetermined control level** (reference standard curve, see section 2.9.2, page 60; a reference threshold level of 10 ug/ml (see page 79, section 3.1.3, paragraph 1, line5; and a threshold level for seropositivity of IgG2 (see page 79, second

paragraph, line 5; and Figure 3.4, page 81; as well as suitable age and sex matched controls (see page 84, paragraph 2, last here lines)).

Additional comparisons were made with respect to the determined IgG2 levels (see page 156, Figure 7.1 frame b); page 165, Figure 7.6 and page 158, section 7.1.2 "The most pronounced reduction was with IgG2 antibodies where 52% of patients showed reduced levels of specific IgG2" after treatment but were patients suffering from H.pylori infection due to unsuccessful treatment, and the control level being pretreatment levels of 7.9 ug/ml (last paragraph page 158))

wherein infection with H.pylori has been associated with forms of gastric cancer (line bridging pages 88-89; also see page 90, Chapter 4, first paragraph, discussion of progression toward gastric carcinoma (also see section 4.2, page 94; section 4.4, page 102, paragraph 3; pg 109, paragraph 1).

Instant claim 36: The method of that comprised determining IgG2 was carried out with another method, specifically microbiological culture together with bacterial Gram stain (see page 81, Figure 3.4, narrative lines 3; page 89, the "gold standard" histology and culture) and/or endoscopy (see page 91, paragraph 1, last line) which gave an indication of H.pylori status (see page 81, Figure 3.4, line 2; also page 91, paragraph 1, last line). ^{13}C Urea Breath test was also carried out along with the serodiagnosis assay method (see page 82, section 3.22) to give an indication of H.pylori infection status.

Instant claim 39, 42, 45: The method for IgG2 was detected by an ELISA method (see page 81, Figure 3.4) that can be considered to be a near-subject type assay (see for example: kit assays, on page 85, Table 3.3)the assay utilizing an antibody, with an enzyme label (see page 75, first paragraph).

(**Instant claim 49-50**) The presence of white blood cell populations was analyzed, specifically T-lymphocytes, and B-lymphocytes associated with the blood cell containing biopsy samples (see Table 2.3, page 68 and immunohistology analysis, page 67, section 2.13.2; also see Chapter 8, sections 8.1 and 8.11 "local immune responses" in gastric biopsy samples; page 184, section 8.1.4; see page 198, paragraph 1, "low levels of IgG2 and IgG4" due to the distribution of "immunocytes producing antibodies"; page 201, paragraph 3). Unwanted debris was removed, so as to enrich the population of cells being detected, through washing the sample three times (see page 67, lines 3-4). It is known that T-lymphocytes and B-lymphocytes are stimulated by IL-4 and B-cells are also stimulated by gamma-IFN (see page 203, paragraph 2).

Inherently Stacey discloses the instantly claimed method, in light of the fact that Stacey shows the determination of IgG2 antibody levels that are reduced in patients with chronic H.pylori infection (see Stacey chapter 7) and shows increased risk of cancer to be associated with H.pylori infection.

16. Claims 23, 29, 31, 37, 40,43, 46, 48-50, 52, 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Karttunen et al (1995) as evidenced by Deltenre et al (1995)

Instant claims 23, 29, 31, 34,48-49, 54: Karttunen et al disclose the instantly claimed invention directed to a method that comprises the steps of:

a) determination of gamma-IFN level(see page 344, Figure 1) in a biological sample (see page 342, col. 2, paragraph 3, "secreted cytokine. IFN gamma", the secreted sample being from blood cells (see page 342, col. 2, paragraph 2)) obtained from an H.pylori infected subject (see title) and compared with an control level;

b) comparison of the gamma-IFN level with a predetermined control level (the control being H.pylori negative gastritis patients), wherein the level of H.pylori positive gastritis patient levels were significantly reduced relative to the control.

Instant claim 37: The method of that comprised determining gamma-IFN was carried out with another method, specifically endoscopy (see page 342, col. 1, paragraph 1) together with histological analysis (see page 342, col. 1, paragraph 2) which provided an indication of H. pylori status (bottom of paragraph "H.pylori was estimated (positive versus negative)".

Instant claim 40, 43 and 46: The method for gamma-IFN was detected by an ELISPOT method (see page 342, col. 2) that can be considered to be a near-subject type assay, the assay utilizing an antibody, with an enzyme label (see page 342, col. 2, paragraph 3, bottom "streptavidin alkaline phosphatase", a type of ELISA (enzyme linked immunosorbant assay).

Instant claim 50, 55: The white blood cells were is purified from the sample of cells to produce an enriched white blood cell population (see page 342, col. 1-2 "extraction of the antral mucosal cells" were treated with "heparin" to prevent blood clotting (see page 342, col. 1, paragraph 3, line 4) which resulted in a "cytospin preparation n" . The cytospin preparation was enriched in T-lymphocytes (see page 343, col. 1, paragraph 2 and table at top of page that compares numbers of "T cells" in normal and gastritis patient samples).

Instant claim 52: the frequency of the gamma-IFN producing cells was determined (see page 343, col. 2, paragraph 3) with cells that were in contact with H.pylori infecting cells in vivo, or in the case of the control, were stimulated with SEB antigen (see page 342 col. 2, paragraph 2 "staphylococcal enterotoxin B").

Inherently Kattunen et al disclose the instantly claimed method as the references discloses the same or equivalent methods steps carried out by the instantly claimed method and obtained the same or equivalent immunoassay results utilizing patient and control samples to assess gammaIFN associated with a human pathogen that causes chronic inflammation and produces diseases associated with stomach carcinoma due to longterm consequences of H.pylori infection (see Kattunen et al, page 341, col. 1, bottom half of column).

17. Claims 24, 29,32,35,38, 41,44, 47, 48-50, 53,54,55 are rejected under 35 U.S.C. 102(b) as being anticipated by Fan et al (1995).

Fan et al disclose the instantly claimed method that comprises the steps of:

Determining IL-4 levels in a blood sample (see Table 2 and 3, page 280) of stimulated lymphocytes (H.pylori antigen added, see Tables 2-3 and narrative on page 291, col. 1, paragraphs 1-2) that have been purified from a peripheral blood lymphocyte sample or gastric biopsy (see abstract) from H.pylori infected patients and from uninfected negative control subjects;

Comparison of the IL-4 level produced the H.pylori positive patients with a predetermined negative control level of IL-4 (negative control subjects, see Tables 2-3, page 290), wherein the level of IL-4 in the H.pylori infected patients was elevated over the control (see Table 3 and narrative on page 291, col. 2, paragraph 2).

Instant claim 38: An additional method to determine status of H.pylori infection was carried out, specifically a rapid urease test combined with a histological examination using a Giemsa stain for the presence of H.pylori infection (see page 289, col. 2, "Subjects" section)

Instant claim 41, 44,47: The IL-4 enzyme immunoassay (EIA) was measured with a commercially available kit, a type of near-subject assay, an immunoassay being an antibody assay with an enzyme label, and considered to be an enzyme linked immunosorbent assay (ELISA).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al (1995), as applied to claims 24, 29,32,35,38, 41,44, 47, 48-50, 53,54,55 above in view of Itoh et al (1999).

See discussion of Fan et al above. Fan et al show a method of determining the presence and amount of IL-4 associated with H.pylori infection based upon stimulation of human cells with Helicobacter pylori antigen, wherein the stimulated cells were from gastric mucosa (biopsy tissue), and IL-4 was determined with an immunoassay (see Table 2 and Table 3, page 290; Measurements, page 290, col. 1, EIA kits) but differs from the instantly claimed invention by failing to show the immunoassay to be a flow cytometry immunoassay for IL-4.

Itoh et al show a flow cytometry immunoassay to detect IL-4 producing T-cells stimulated with H.pylori antigen in an analogous art for the purpose of determining cell production of IL-4 due to H.pylori infection.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the immunoassay of Fan et al that detects IL-4 with the immunoassay of Itoh et al that detects IL-4 by flow cytometry because Itoh et al teaches the importance of analysis of cellular events mediated by T cells in the stomach of a H.pylori infected patient (see page 561, col. 1, paragraph 1, Itoh et al) because T cells produce cytokines in response to H.pylori antigen, through receptor activation which in turn are important in the regulation of inflammation and clinical outcome of the infection.

In the absence of a showing of unexpected results, the person of ordinary skill in the art would have been motivated by the reasonable expectation of success of determining the level and amount of IL-4 in a cell sample obtained from the gastric mucosa of an H.pylori infected patient, relative to values produced by healthy donors because Itoh et al successfully detected and analyzed multiple cell samples obtained from the gastric mucosa of H.pylori infected patients utilizing multicolor flow cytometry through utilization of an automated flow cytometer (Epics XL; Coulter Electronics, Miami, Florida, USA (see page 561, col. 2, paragraphs 2-3, Itoh et al). Fan et al in view of Itoh et al obviate the instantly claimed invention.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
21. Deltenre et al teach H.pylori infection correlates with increased risk of cancer (see title, see page 194, col. 1, paragraph 1 and page 197, col. 1, paragraph 1).
22.
23. Mohammadi et al (1996) discloses a method that determines IgG2, gammaIFN and IL-4 levels (see materials and methods, figures and tables) and teaches H.pylori infection is associated with increased risk of Gastric cancer.
24. Fan et al (1996) is cited to show the determination of IL-4 to be increased in H.pylori infected patients as compared to controls, and IL-4 is known to inhibit the synthesis of gammaIFN (see page 38, col. 1, middle of paragraph 1).

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 28, 2005

L. F. Smith

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